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10/038,284	01/02/2002	Ralf Ehricht	15111.0066	6813

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EXAMINER	
FORMAN, BETTY J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,284	EHRICHT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,25,27,29-37,39-45 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-19,25,27,29-37,39-45 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 October 2007 has been entered.

Status of the Claims

2. This action is in response to papers filed 9 October 2007 in which claims 2, 17, 40-41, 45 were amended and claims 26, 28, 38, 46, 48-50 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 11 April 2007 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous objections to Claims 17, 28 and 38 are withdrawn in view of the amendments and/or canceled claims. The previous rejections under 35 U.S.C. 102 and 35 U.S.C. 103, not reiterated below, are withdrawn in view of the amendments and/or Applicant's comments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1-19, 25, 27, 29-37, 39-45 and 47 are under prosecution.

Claim Objections

3. Claims 27 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claims depend from canceled Claim 26.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5, 8-15, 17-19, 25, 27, 29-30, 34-36, 39-45, 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999).

Regarding Claim 1, Stapleton et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip having a detection area within an optically permeable zone of detection (Column 14, lines 40-57), the detection area including an array of multiple different nucleic acids immobilization (Column 5, lines 40-44), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), an inlet for liquid introduction (Column 6, lines 10-15) whereby a continuous cavity forms a single reaction

chamber adapted to amplify and characterize nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57).

Regarding Claim 2, Stapleton et al disclose the device further comprising a temperature adjustment means connected to the chamber adapted to permit temperature control (e.g. temperature sensor and valves, Column 13, lines 16-25).

Regarding Claim 3, Stapleton et al disclose the device wherein the temperature adjustment means are on the sidewalls of the chamber (Column 13, lines 57-60).

Regarding Claim 4, Stapleton et al disclose the device the detection zone includes detection spots (i.e. probe array) and the temperature adjustment means does not affect the transparency of the chip i.e. on the sidewalls of the chamber (Column 13, lines 57-60 and Column 14, lines 36-57).

Regarding Claim 5, Stapleton et al disclose the device wherein the heating elements comprise micro-structured elements (Column 14, lines 9-17).

Regarding Claim 8, Stapleton disclose the device wherein the chamber support and body consist of optically permeable material e.g. glass (Column 14, lines 40-57).

Regarding Claim 9, Stapleton disclose the device wherein the chamber support consists of thermally conducting material (Column 13, lines 57-60).

Regarding Claim 10, Stapleton disclose the device wherein the chip consists of optically permeable material e.g. glass (Column 14, lines 40-57).

Regarding Claim 11, Stapleton et al disclose the device further comprising an optically permeable conical recess in the detection area (inverted cone #28, Column 9, lines 50-59).

Regarding Claim 12, Stapleton et al disclose the device further comprising spatially separate inlet (#20) and outlet (#30).

Regarding Claim 13, Stapleton et al disclose the device wherein the spatially separate inlet (#20) and outlet (#30) are arranged unilaterally to the chip (Fig. 1) and separated by a gas reservoir (i.e. inflatable valve, Column 13, lines 26-40).

Regarding Claim 14, Stapleton et al disclose the device wherein the chamber is sealingly connected to the support by an adhesive (Column 5, lines 45-54).

Regarding Claim 15, Stapleton et al disclose the device wherein the detection area is configured in spots of immobilized probes i.e. arrayed probes spaced by a few microns (Column 5, lines 40-44).

Regarding Claim 17, Stapleton et al disclose the device wherein the detection area is configured in the form of spots onto which probes are immobilized (i.e. probe array, Column 14, lines 36-43).

Regarding Claim 18, Stapleton et al disclose the device configured for optical detection (Column 14, lines 40-45).

Regarding Claim 19, Stapleton et al disclose the device is adapted to allow various forms of detections via optical and non-optical methods (Column 14, lines 40-54). The instantly recited "by a silver precipitation reaction" does not describe or define a structural component of the device. Because the recitation "by a silver precipitation reaction" does not further define the device, Stapleton anticipates the claimed invention.

Regarding Claim 25, Stapleton et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip having a detection area within an optically permeable zone of detection (Column 14, lines 40-57), the detection area including an array of multiple different nucleic acids immobilization (Column 5, lines 40-44), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), an inlet for liquid introduction (Column 6, lines 10-15) whereby a continuous cavity forms a single reaction chamber adapted to amplify and characterize nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57).

Regarding Claim 27, Stapleton et al disclose the device wherein the optically permeable chip includes a detection area having immobilized probes within a gap (chamber) (Column 5, lines 40-64).

Regarding Claim 29, Stapleton et al disclose the device wherein the detection area is optically permeable (Column 14, lines 40-45).

Regarding Claim 30 Stapleton et al disclose the device wherein the chamber is temperature adjustable and flow controllable (Column 12, line 62-Column 13, line 60 and Column 14, lines 14-23).

Regarding Claim 34, Stapleton et al disclose the device wherein the chamber body includes polycarbonate or polymethylpentene (Column 11, lines 18-20).

Regarding Claim 35, Stapleton et al disclose the device wherein the chamber body includes a sealing surface adapted to releasable connect to the support e.g. adhesive or clamping mechanisms (Column 5, lines 50-54 and Column 12, lines 8-25).

Regarding Claim 36, Stapleton et al disclose the device wherein the nucleic acids include one of DNA or RNA i.e. nucleic acids for the analysis of genes or gene expression, Column 4, lines 25-31).

Regarding Claim 39, Stapleton et al disclose the device wherein the optical detection includes fluorescent detection (Column 14, lines 35-57).

Regarding Claims 40-43, Stapleton et al disclose the device wherein the device is suitable for reactions e.g. amplification, thermocycling, antibody binding, expression analysis, enzymatic reactions, etc. (abstract, Column 4, lines 11-37, Column 15, lines 2-20). The instantly claimed "adapted to perform" does not define or describe structural elements of the device. Because Stapleton et al specifically teach the structural elements of Claim 1, because Stapleton et al teach various reactions performed within the device, and because the instant claims do not define further structural components of the device, Stapleton et al anticipate the device as claimed.

Regarding Claim 44, Stapleton et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip having a detection area within an optically permeable zone of detection (Column 14, lines 40-57), the detection area including an array of multiple different nucleic acids immobilization (Column 5, lines 40-44), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), an inlet for liquid introduction (Column 6, lines 10-15) whereby a continuous cavity forms a single reaction chamber adapted for reacting and characterizing nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57) and further a sample inlet (#20) and outlet (#30) are connected to the single chamber (Fig. 1).

Regarding Claim 45, Stapleton et al disclose the device wherein the gap includes means for reacting the sample (Column 14, line 58-Column 15, line 20).

Regarding Claim 47, Stapleton et al disclose the device wherein the chamber is free of fluid channels to move the nucleic acids to a subsequent chamber (Fig. 1).

Response to Arguments

6. Applicant states that the instant claims are drawn to a device having a continuous cavity consisting of a single chamber for both reaction (or amplification) and characterization of nucleic acids. Applicant asserts that Stapleton's array for characterization is not in the same chamber where amplification occurs and therefore does not anticipate the claimed invention. Applicant points to Column 14, lines 58-63 of Stapleton to support the asserted difference between the reference and the instant invention. The argument has been considered but is not found persuasive. While the cited passage teaches hybridization on another working area, the passage does not define the "another working area" as outside the chamber. Furthermore, the remaining text and claims of the patent does teach reacting and analyzing in the single chamber. The passage immediately preceding that cited by Applicant is presented below (column 14, lines 36-57):

> The chamber embodied in this invention is well-suited for positioning an array because a microprobe array is readily bonded, synthesized or printed on a microscope slide or silicon chip, which surface becomes **one** of the opposing walls of the chamber when it is affixed to the opposing wall comprising the means to control fluid flow. Optically clear walls of glass, clear polymer or the like, permit imaging with scanners and CCD cameras though the wall. Electronic circuits may be printed on glass, silicon or other material to connect each specific probe with a signal-detecting instrument. By affixing the device of the invention with a wall containing a probe array on its surface, such as could be made by light-directed chemical synthesis (Affymetrix, Santa Clara, Calif.) or other means of binding nucleic acid sequences to a surface, the device is capable of **processing samples** with different liquid treatments such as needed for labeling and hybridizing nucleic acid samples. An optically clear wall or window of the device such as glass or clear plastic makes it compatible to be read by a CCD camera imaging system, or other dedicated instruments and software developed to detect fluorescence of high-density arrays of oligonucleotides.

Applicant's attention is also pointed to Claims 6 and 12 of the Stapleton patent, which are drawn to the device having two opposing walls and materials for "reacting and analyzing components of the biological specimens". Hence, Stapleton clearly teaches all the elements of the claimed invention.

7. Claims 25, 27, 29, 30, 44, 45, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Besemer et al (WO 95/33846, published 14 December 1995).

Regarding Claim 25, Besemer et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip (e.g. glass

support, page 6, lines 3-29) having a detection area within an optically permeable zone of detection (e.g. #310, Fig. 3), the detection area including an array of multiple different nucleic acids immobilization (page 7, lines 4-12), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (transparent cover, page 24,lines 19-28), an inlet for liquid introduction (page 6, lines 29-33) whereby a continuous cavity forms a single reaction chamber adapted for reaction (e.g. hybridize) and characterize (e.g. sequence) nucleic acids therein (page 20, lines 23-31).

Regarding Claim 27, Besemer et al disclose the device wherein the optically permeable chip includes a detection area having immobilized probes within a gap (page 24, lines 19-28).

Regarding Claim 29, Besemer et al disclose the device wherein the detection area is optically permeable (page 24, lines 19-28).

Regarding Claim 30 Besemer et al disclose the device wherein the chamber is temperature adjustable and flow controllable (page 13, lines 10-45).

Regarding Claim 44, Besemer et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip (e.g. glass support, page 6, lines 3-29) having a detection area within an optically permeable zone of detection (e.g. #310, Fig. 3), the detection area including an array of multiple different nucleic acids immobilization (page 7, lines 4-12), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (transparent cover, page 24,lines 19-28), an inlet for liquid introduction (page 6, lines 29-33) wherein the device is adapted for reaction (e.g. hybridize) and characterize (e.g. sequence) nucleic acids therein (page 20, lines 23-31) and further a sample inlet and outlet are connected to the single chamber (e.g. Fig. 3, #350/#360)

Regarding Claim 45, Besemer et al disclose the device wherein the gap includes means for reacting the sample (page 20, line 43-page 21, line 4).

Regarding Claim 47, Besemer et al disclose the device wherein the chamber is free of fluid channels to move the nucleic acids to a subsequent chamber (e.g. Fig. 3).

Response to Arguments

8. Applicant asserts that Besemer does not teach a device for both amplifying and characterizing nucleic acids. The argument has been considered and found convincing for the embodiments defined by Claim 1 and claims depending from Claim 1. Claim 1 defines the device as having a chamber for both amplifying and characterizing nucleic acids. The previous rejection of Claim 1 claims depending from Claim 1 is withdrawn. However, the previous rejection of Claims 25, 27. 29-30, 44-45 and 47 is maintained. Claims 25, 27. 29-30, 44-45 and 47 are drawn to a device adapted for reacting and characterizing nucleic acids. Besemer teaches the device adapted for hybridizing and sequencing and detecting and therefore anticipates the claims as detailed above.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) in view of McBride et al (U.S. Patent No. (6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 6 and 7, Stapleton et al teach the device comprising automated fluidic movement (Column 9, lines 9-36 and Column 14, lines 25-35). However, Stapleton is silent regarding a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple electrodes providing a distribution of magnetic poles (Column 3, lines 34-55). Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the electrodes of Stapleton et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

Response to Arguments

11. Applicant reiterates the arguments regarding Claim 1 and asserts that McBride does not cure the deficiencies of Stapleton. The argument is not found persuasive based on the above discussion regarding the teaching of Stapleton.

12. Claims 16, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claims 16 and 37, Stapleton et al teach the device wherein the nucleic acids include one of DNA or RNA i.e. nucleic acids for the analysis of genes or gene expression, Column 4, lines 25-31) and wherein the preferred probe arrays are made using the method of Affymetrix (Column 14, lines 46-49). Stapleton does not specifically teach DNA or RNA probes immobilized through spacers.

However, Fodor et al (i.e. Affymetrix and VLSIPS technology) teach their probes are DNA or RNA (Column 5, lines 32-34) and immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Stapleton et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Response to Arguments

13. Applicant reiterates the arguments regarding Claim 1 and asserts that Fodor does not cure the deficiencies of Stapleton. The argument is not found persuasive based on the above discussion regarding the teaching of Stapleton.

14. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) in view of Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claims 31-33, Stapleton et al teach the device comprising resistive heaters/sensor (Column 14, lines 14-17) but is silent regarding the composition of the resistive heaters. However, nickel-chromium thick film resistive heaters and sensors were well known and routinely practiced in the art at the time the claimed invention was made as taught by

Lipshutz et al (Column 24, line 53-Column 25, line 6). Lipshutz et al further teach their resistive heater composition is capable of producing temperatures in excess of 100 degrees without adverse affects. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the resistive heater composition of Lipshutz et al to the resistive heaters of Stapleton. One of ordinary skill in the art would have been motivated to do so based on the preferred use and benefits taught by Lipshutz et al (Column 24, line 53-Column 25, line 6).

Response to Arguments

15. Applicant reiterates the arguments regarding Claim 1 and asserts that Lipshutz does not cure the deficiencies of Stapleton. The argument is not found persuasive based on the above discussion regarding the teaching of Stapleton.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
December 11, 2007